



NUI Galway
OÉ Gaillimh

The Effect of Structured Exercise on Chronic Venous Insufficiency: A

Feasibility Trial

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Shannon Hernon
National University of Ireland Galway



ABBREVIATIONS

BMI	Body Mass Index
BW	Body Weight
CVI	Chronic Venous Insufficiency
DF	Dorsiflexion
EF	Ejection Fraction
PAR-Q	Physical Activity Readiness Questionnaire
PF	Plantar Flexion
PPG	Photo-plethysmography
PT	Peak Torque
ROM	Range of Motion
RVF	Residual Volume Fraction
SFW	Strength from Within
VRT	Venous Return Time
VT1	Ventilation Threshold 1
VV	Venous Volume

1. STUDY BACKGROUND

Chronic Venous Insufficiency (CVI) results from the disruption of normal blood transportation, whether the disruption occurs in the superficial or deep venous system, the perforating veins or any combination of these¹. When the perforator valves become compromised, pressure in the calf muscle contraction increases and blood begins to flow through the compromised perforator veins into the superficial venous system resulting in venous hypertension or varicose veins¹. Varicose veins are known as common venous incompetence in the lower extremities and appear as dilated, elongated, or winding superficial veins². Venous pressure in the lower legs results from damaged deep, superficial and or perforating veins and over time this can lead to changes in the skin such as hyperpigmentation, edema, and can lead to ulceration². It is essential for individuals to have regular contraction of the calf musculature as it controls lower extremity venous return². The calf muscle pump function is known as the “peripheral heart” for its crucial role in an individual’s calf muscle pump function⁴. Once there is long-term weakness in the calf musculature the blood flow to the lower extremity slows down and increases the risk for a deep venous thrombosis². With many theories leading to the valve reflux being the main cause of varicose veins there has been no evidence to show that if the compromised primary valve initiates the process of varicose veins or if the dilatation or weakening of the vein walls and collagen composition is the cause.

CVI is a highly reported chronic medical condition in the United States and the Western world¹. In the United States alone over 2.5 million individuals are affected by chronic venous disease with prevalence ranging in geographical locations^{1,3}. Beebe-Dimmer et al (2005) reported that over a wide variety of countries from 1942-2003 the prevalence of varicose veins varied from 2% to 56% in men and from <1% to 73% in women. However, in 2017 a decrease was reported that prevalence of CVI varied from <1% to 40% in women and from <1% to 17% in men³. CVI impacts countries financial status as wound care alone in the United States allots for 3 billion dollars annually³.

There are many factors that put individuals at risk for the development of chronic venous insufficiency, such as, advancing age, family history of venous disease, ligament laxity, prolonged standing, increased BMI, smoking, sedentary life style, lower-extremity trauma, prior venous thrombosis, the presence of an arteriovenous shunt, some hereditary conditions, high levels of estrogen and pregnancy^{1,5,6,7-20}.



Once diagnosed, treatment for CVI is a conservative management by reducing symptoms and preventing progress of the disease and secondary complications²¹. Initial conservative treatments consist of leg elevation, exercise therapy and compression to improve oxygen transport to the skin and subcutaneous tissues, decrease edema, reduce inflammation, and compress any dilated veins²². It is recommended that individuals with CVI maintain an ideal body weight or reduce their weight, if overweight, and maintain an overall healthy lifestyle¹⁹. Exercise is a recommended form of therapy for individuals with CVI as it can help improved calf muscle pump function²³.

In a clinical setting CVI is diagnosed through the use of the CEAP classification. The CEAP scoring is made up of four clinical components, (C)clinical signs, (E)Etiology, (A) Anatomy and (P)Pathophysiology. Each component of the CEAP classification have numerical subcomponents of their own. Within the clinical settings there are eight subcomponents, (C0) no visible or palpable signs of venous disease, (C1) telangiectasia/reticular veins, (C2) varicose veins, (C3) edema, (C4) Pigmentation or eczema, (C5) healed venous ulcer, (C6) active venous ulcer²⁴. In the etiology there are four subcomponents, (Ec) congenital, (Es) secondary, (En) etiology not specified²⁴. The anatomy component of the CEAP classification is broken down into four subcomponents, superficial venous system (As), perforating veins (Ap), deep venous system (Ad) and anatomy not specified (An)²⁴. The pathophysiology component is made up of four subcomponents, venous reflux (Pr), venous obstruction (Po), venous reflux and obstruction (Pr,o) and reflux not specified (Pn)²⁴.

In regards to this study a CEAP score of C2, C3 and C4 will be included within the inclusion criteria. The C2 clinical classification is identified as varicose veins which are subcutaneous dilated veins 3mm or more. Edema or C3 is common among individuals with chronic venous insufficiency due to the increased volume of fluid in the skin and subcutaneous tissues, venous edema is commonly found in the ankle²⁴. C4 is divided into two categories, C4a is known as pigmentation or eczema where the skin will have a brown/darkening pigmentation due to the hemosiderin deposition a result from the discharge of red blood cells typically occurring in the ankle region²⁴. Eczema is typically located near the varicose veins and begins as an erythematous dermatitis and has the potential to progress as blisters²⁴. C4b or

lipodermatosclerosis (LDS) is localized chronic inflammation and fibrosis of the skin and subcutaneous tissue of the lower extremities²⁴.

2. STUDY RATIONALE

Compression leg garments have become the mainstay for conservative management of CVI. It was found that treatment with a 30-to 40-mmHg compression stocking results in improvement in pain, swelling, skin pigmentation, activity and well-being if compliance of 70%-80% is achieved²¹. Compression therapy is the first line of treatment that is implemented for individuals with chronic venous insufficiency²¹. Individuals with CVI face a number of complications, such as, muscular dysfunction, limited ankle range of motion(ROM) and diminished calf

muscle pump function²³. Exercise therapy has been shown to improve calf muscle pump function and symptoms and may provide additional therapeutic benefits²³. It has been reported that structured exercise has the ability to improve ankle joint range of motion, calf muscle strength and calf muscle pump function. However, the majority of structured exercise programmes strictly focus on the lower trunk and lower leg strengthening. Focusing on one aspect of the body only when participating in structured exercise has the potential to be harming to an individual's kinetic chain and posture. A combination of upper and lower body structured exercise as well as, ankle joint range of motion and a walking regimen has the potential to have a significant impact on an individual's calf muscle pump function and avoid these potentially harmful side effects of lower body exercise programmes

Structured Exercise and Calf Muscle Pump Function in CVI

Padberg, Johnston and Sisto (2004) conducted a study hypothesising that structured exercise would improve calf muscle pump function, calf muscle strength and venous hemodynamic in patients with chronic venous insufficiency. All patients were clinically diagnosed with advanced CVI and a CEAP score of 4,5,6 all determined through a duplex ultrasound scanning²³. Patients with an ulceration greater than 4 cm in diameter, painful ulceration, active local infection, recognized noncompliance, absence of objective evidence of a venous cause, uncompensated cardiorespiratory insufficiency, ABI less than 0.7, and recent venous thrombosis were excluded from the study²³. A total of 77 patients were screened for the study, 46 participants were excluded, there was a total of 30 trial subjects and a total of 28 participant data was analysed²³.

Patients underwent air plethysmography (APG) to evaluate reflux volume, outflow, and calf pump function as well as ankle isokinetic dynamometer. Investigators used a Biodex System 2 multi-joint and rehabilitation system to obtain data for calf torque, work, power and range of motion²³. Ankle plantar flexion and extension were tested on the Biodex twice, one week apart at two separate speeds, slow (60 degrees per second) with full ankle dorsiflexion and fast (120 degrees per second) with full ankle plantar flexion²³. All patients completed five repetitions at the slow speed and fifteen repetitions at the fast speed, all tests were replicated from Sisto et al and Holback et al²³. Measurements collected were the average of all

contractions for peak torque, peak torque per unit of body weight, maximal repetition work, total work, average power, and maximal range of motion²³. All patients underwent functional and quality of life assessment through the administration of the Aberdeen Varicose Vein Survey, CIVIQ, the physical function terms of the SF-36 Health Survey, the functional independence measure, Craig Handicap and reporting techniques, and older American resources to test for function in daily life²³. All questionnaires were administered at 0 (baseline) and 6-months (completion of the study)²³. Participants were then randomly allocated into two unblinded groups; the control group or the therapy (experimental) group.

Participants randomized into the exercise prescription group received 3-months of supervised exercise therapy followed by 3-months of unsupervised exercise therapy. At baseline, 3 months and 6 months clinical examinations, APG, and isokinetic dynamometry were performed²³. The supervised exercise programme consisted of lower limb and trunk stretching and strengthening, active gravity strengthening and resistance weights in two sessions each week each lasting for approximately one hour²³. All exercise programmes and prescriptions were individualized by the physiotherapist. Exercise training focused on the strengthening of lower leg, specifically, calf musculature and progression was monitored by repetitions, sets and weights throughout the duration of the exercise programme. In each session uphill treadmill walking was incorporated in the supervised training programme and participants were encouraged to continue uphill walking in the final 3-months of unsupervised exercise training. Compliance to the exercise programme was documented by the number of days the participants attended the supervised exercise sessions and in the unsupervised exercise phase the number of days of exercise completed or not²³. Patients in the usual care control group underwent baseline measurements at 0 and again at 6 months. The control group was monitored monthly to confirm and ensure participants were using their compression stockings²³. Upon completion of the 6-month programme participants in the control group had the opportunity to take on the 6-month supervised exercise therapy as wait-listed participants²³.

Padberg, Johnston and Sisto (2004) compared the experimental group with the control group and found that the ejection fraction (EF) increased significantly ($P<.026$) and the residual volume fraction (RVF) decreased significantly ($P<.029$)²³.



After 6-months it was reported that there was no significant change in venous clinical severity score and outflow fraction or obstruction²³. When compared to the control group, the exercise group improved their mean peak torque per unit body weight as well as slow and fast peak torque²³. A univariate ANOVA was performed controlling baseline values found a difference for slow speeds ($P<.053$) and fast speeds ($P<.033$)²³. However, when compared at 6-months there was no significant difference between the two groups for other Biodex measurements²³. Between the two groups there were no significant differences observed in QOL, functional or perceived impairment²³. The structured exercise group experienced improved calf muscle pump function and dynamic calf muscle strength after 6-months²³. Calf muscle strength was improved at both speeds slow and fast when normalized to body weight²³. Padberg, Johnston and Sisto (2004) stated that direct physical conditioning of the calf musculature may prove beneficial for patients with or without alternative management options for severe CVI.

The primary limitation faced in this study was the low number recruited to the study, 30 instead of planned 60, which was the target number of participants. Within the two individual groups there were limitations of their own; there was a nonsignificant pattern of greater medical comorbidity and greater musculoskeletal complications in the experimental group²³. From the research conducted it is suggested to have a greater sample size and a multisite study to confirm and clarify the effects of physical therapy on CVI, the effects on QOL, and benefit for the participants²³.

Effects of isokinetic on calf musculature in patients with CVI

Ercan et al (2017) conducted a study observing the change of ankle joint range of motion, muscle strength values of plantar flexion and dorsiflexion measured with an isokinetic dynamometer, Visual Analog Scale (VAS) scored, EQ-5D quality of life scale, and venous return time in individuals clinically diagnosed with CVI after a 12-week exercise intervention²⁹. There was a total of 27 patients included in the study, 23 female and 4 male, five patients left the study due to inadequate compliance with the exercise programme as a result 22 patients were included in a statistical analysis²⁹.



All patients were diagnosed with a CEAP 3 and 4 determined by the patients' medical history and findings from a physical examination, Doppler ultrasonography and photo-plethysmography (PPG) testing²⁹. Patients with painful ulcer venous ulceration, active local infections, the patient incompatibility during the test, non-compensatory heart and lung failure, peripheral arterial disease, diabetes, vasodilator treatment, orthopaedic disorders of the ankle, and any systemic disease were excluded²⁹. Before and after the 12-week exercise programme all patients had their ankle joint range of motion assessed, quality of life and PPG testing all baseline measurements were employed in the same order²⁹.

The structured exercise programme consisted of an isokinetic exercises for the calf musculature for three days a week for 12-weeks²⁹. The exercise programme was made up of range of motion exercises (10 reps X 3 sets), thera-band exercises (10 reps X 3 sets, flexion-extension-internal and external rotation), isokinetic exercise (three different speeds 60°, 90°, 120° for 10 repetitions for 3 sets), stability exercise on balance board (10-minutes), treadmill walking (60% HR max for 20-minutes), intermittent pneumatic compression (JOBST for 20-minutes)²⁹. Ankle plantar flexion and dorsiflexion were tested at speeds of 60-120°/s in concentric/concentric mode all tests were applied in a prone position at a range of motion of 15° dorsiflexion and 40° plantarflexion²⁹.

PPG measurements for all patients included in the study were conducted by a cardiovascular surgeon. VAS scoring was used to determine the severity of the patients CVI and the EQ-5D quality of life survey was used to understand the effect CVI has on the individuals quality of life²⁹. Ankle joint range of motion measurements were measured by a metal goniometer prior to isokinetic muscle strength measurements²⁹. Before participating in the muscle strength test patients underwent submaximal warming exercises on the cycle ergometer for 10 minutes, followed by stretching exercises for five minutes²⁹. Peak torque and total work values of ankle plantar flexion and dorsiflexion were measured by isokinetic testing²⁹.

As mentioned there were 27 patients included in the study; at the end of 12-weeks five patients were excluded due to inadequate compliance to the exercise programme leaving 22 patients for statistical analysis. An dependent *t-test* was performed found a significant increase ($p < 0.05$) in the participants venous return times (VRT)²⁹. Ankle ROM increased significantly ($p < 0.05$) as well as an increase in

peak torque (PT), PT/BW, total work done in PF and DF and a significant decrease in agonist/antagonist ratio through isokinetic measurement ($p < 0.05$)²⁹. Ercan et al (2017) found that the 12-week at home exercise programme decreased participants VAS values and a significant increase in EQ-5D quality of life scale ($p < 0.05$)²⁹. However, the study failed to positively impact participants calf muscle pump function in regards to venous reflux. After 12-weeks of structured calf muscle exercise participants experienced improved ankle ROM, improved muscular strength, overall improved QOL, improved VRT and reduction of pain²⁹. After 12-weeks of structured exercise it was reported, exercise has a positive impact in the treatment of venous insufficiency²⁹.

Isokinetic testing is necessary and highly beneficial when evaluating muscle performance. Measurements are obtained by the machine performing kinematic analysis of movements and comparing both sides of the extremity through agonist/antagonist muscle strength and the work capacity and endurance of muscle movement²⁹. Manual muscle testing does not provide accurate and reliable values, this form of testing only establishes the force which occurs at a certain point of movement. Data such as work, force, and endurance are immeasurable, it was reported a 23%-31% deficit was found in isokinetic knee testing in patients who reportedly had normal values in manual testing²⁹. Isokinetic testing is a musculoskeletal performance system that has the ability to compute reliable quantitative data and provide the option to save the patients data to evaluate the disease progression or improvement²⁹. Isokinetic testing is highly beneficial to this study and patient population as it assists in the evaluation of muscular strength in which can aid in the improvement of calf muscle pump function and ankle ROM which can also contribute to the improvement of calf muscle pump function in individuals with CVI.

Adequate ROM is as important in healthy individuals as it is in individuals with CVI. With long periods of inactivity muscles tend to shorten, resulting in tightness of the muscle. ROM is then negative affected by these tight muscles restricting the joint from reaching the full range. Ercan et al (2017) stated that the slightest change in ROM has the potential for greater hemodynamic changes. It is reported that a change of 1.5 cm in ankle rotation axis leads to 8.3% increase in extension PT³⁰. There is a positive correlation between an individual with CVI and their ROM and the

stage of venous disease they may be experiencing³¹. It is recommended for individuals with CVI to incorporate ankle exercises into their daily lives as they can be highly beneficial to ROM improvement and calf muscle contraction²⁹.

It is important for individuals participating in a new exercise intervention that the exercise technician incorporates all movements that an individual will experience in a day, such as, bending and lifting, single leg movements, pushing, pulling and rotation. Both studies discussed did not incorporate an upper-body movement or intervention. An exercise intervention should include all the daily movements mentioned above it and it should also include the appropriate open-chain and close-chain movements to ensure the body is moving and growing in unison. By incorporating upper and lower body exercises, aerobic exercise and range of motion into an exercise programme the individual will receive a well balance approach to exercise and maintain proper posture and alignment within their kinetic chain.

The “Strength From Within” (SFW) programme incorporates upper and lower body exercise both assisted and non-assisted as well as open-chain and closed-chain movements. This is a 12-week at home based structured resistance exercise programme which has the ability to be modified to different exercise intensities and individual abilities. Participants will have the choice of how many repetitions they complete for each exercise, if they need to be sitting or standing for certain exercises and when in their day they want to complete the exercises. The SFW programme consists of a total of twenty exercises made up of upper and lower body exercises both sitting and standing. Participants will be asked to complete lower body exercises on Monday, Wednesday and Friday and upper body exercises Tuesday, Thursday and Saturday and Sunday as a rest and recovery day. Incorporated with resistance programme are ankle ROM exercises, a warm-up and cool-down, and a walking protocol. This exercise intervention is a full body at home resistance and aerobic programme that has the potential to improve calf muscle pump function, venous clinical severity score, calf muscle strength, greater ankle range of motion, overall physical strength and quality of life.



3. STUDY HYPOTHESIS

Implementation of a 12-week at home structured exercise and aerobic programme will produce physiological and psychological benefits in individuals with chronic venous insufficiency.

4. STUDY DESIGN

Feasibility Study; Cohort Prospective



5. STUDY OBJECTIVES

Following the terms of PICO (Population; Intervention; Comparator; Outcome) the primary research question for this trial is: in adult patients with chronic venous insufficiency can a 12-week at home structured exercise and aerobic programme improve calf muscle pump function, venous clinical severity score, calf muscle strength, greater ankle range of motion, overall physical strength and quality of life.

5.1 Research Aim To determine the feasibility of a 12-week at home structured resistance and aerobic exercise programme.

5.2 Research Objectives

- i. To determine if structured exercise results in improves calf muscle pump function and the magnitude of change in calf muscle pump function
- ii. To determine if structured exercise results in improved venous clinical severity score and, if so, the percentage of participants who achieve an improved score.
- iii. To determine if structured exercise results in increased calf muscle strength and the magnitude and range of same and the percentage of participants who achieve an improved score.
- iv. To determine if structured exercise results in improved ankle range of motion and the magnitude and range of change between time 0 and at end of study.
- v. To determine the response rate and completion rate of participants
- vi. Time needed to collect measurements
- vii. Time needed to instruct participants in exercises of “strength from within” programme and provide individualised plan for participants.
- viii. Time per week of phone contact.
- ix. Adherence to weekly exercise regimen in terms of days per weeks, duration per day and number and type of exercises completed per day. To determine if structured exercise results in increased overall physical strength
- x. To determine if structured exercise results in improved quality of life

6. STUDY DESIGN

6.1 Statement of Design

A feasibility study on the effect of a 12-week at home structured resistance and aerobic exercise programme in individuals with chronic venous insufficiency.

6.2 Study Procedure

There will be a total of sixty participants recruited for the study, with an anticipation of 40 to complete the study. Participants will complete the Physical Activity Readiness Questionnaire (PAR-Q) to ensure that they are able to participate in the structured exercise programme. If the participants' answers "yes" to any question on the Physical Activity Readiness Questionnaire (PAR-Q), he/she is ineligible to participate. Participants will also read a participant information leaflet and sign an informed consent before participating in the study. Baseline demographic will be collected at the start of the study. Participants will complete the SF-36 Health Survey at session one and session 2 (week 12). Baseline testing will be conducted. The following measures will be employed in the study through a baseline testing and repeated at the end of the study period (week 12): Functional ambulatory measurements, physical activity measurements, isokinetic testing, duplex ultrasound screening.

Upon completing baseline testing participants will have the warm-up, cool-down, stretches, all exercise demonstrated and explained to them. Participants will go through each exercise with the principal investigator to ensure understanding. The principal investigator will then describe each section of the "Strength From Within" Booklet. At the end of the first session the participants will be administered their at home structured exercise booklet, recording booklet, resistance band, warm-up and cool-down information sheet and their ankle range of motion information sheet.

The baseline meeting and the week 12 meeting will take roughly 90 minutes to complete all baseline measurements, questionnaires, isokinetic testing and demonstrations. Isokinetic testing will take a total of 32 minutes with resting periods included in the time, baseline measurements including the muscle strength and functional ambulatory measurements will take a duration of 10.5 minutes, demonstration of the home structured exercise programme will take up to 20 minutes, both questionnaires will take 5-minutes total and time left for any other

questions or concerns. Extra time will be given at any point during both meetings if needed by the participant.

6.3 Selection of Participants

Participants will be screened by Professor Sherif Sultan at his vascular clinic using the inclusion/exclusion criteria.

6.4 Participant Recruitment

Through the vascular clinic of Professor Sherif Sultan at Galway Clinic Hospital. Professor Sherif Sultan will screen the patients with the inclusion and exclusion criteria. Once patients are screened and eligible for recruitment and expressed interest in being contacted by study researcher, with their permission Professor Sherif Sultan will provide their contact information to the study researcher, who will then contact the patient to arrange meet at a time convenient to the patient. At that meeting, the patient will receive the PIL to read. Any questions will be answered by the study researcher. If the patient wishes to participate he/she will sign 2 copies of the consent form, which will also be signed by the study researcher. A signed copy of the consent form will be given to the participant along with the PIL.

6.5 Inclusion Criteria

Adult patients with chronic venous insufficiency and a CEAP Score of 2,3,4.

6.6 Exclusion Criteria

- i. Younger than 18 years
- ii. Painful Ulceration
- iii. Severe Cardiac Condition
- iv. Cardiorespiratory Disease
- v. Failure of Physical Activity Readiness form
- vi. ACSM Risk Classification: Class C or above
- vii. CEAP classification of 5 or 6
- viii. Severe mobility impairment
- ix. Severe imbalance
- x. Women who are pregnant



- xi. Women who are breastfeeding
- xii. Those who lack capacity to consent
- xiii. Those for whom English is not the first language and have difficulty understanding written and/or spoken English
- xiv. Diagnosis of diabetes
- xv. Diagnosis of peripheral arterial disease
- xvi. Diagnosis of peripheral neuropathy

6.7 Selection of Patients

Patients will be recruited from vascular surgery clinic at Galway Clinic Hospital

6.8 Informed Consent

An informed consent will be provided to the patients and will be signed and obtained by both the investigator and the participant. Consent to participate in the trial will be obtain from each patient after full explanation and consideration of the trial. A copy of the signed consent form will be given to the participant and a copy will be kept secure by principal investigators. Participants will also be given a written information sheet about the study. It is the individuals' right to withdraw from the trial at any point without reason. The informed consent will meet and withhold principals and requirements of the approving research ethics committee.

Informed consent for patients

Following verbal explanation of the study possible participants will be given time within the first meeting to consider participation. If the participant requests more time to consider participation then they will ask to contact the study researcher whose contact details are on the PIL at a time that suits them to either answer any further queries, agree to participate or otherwise. If they decide they do not want to participate then it will not be necessary to contact the study researcher unless they wish to do so. It is anticipated that most eligible patients who agree to meet will decide at the initial meeting if they wish to participate and there will be no time restriction at this meeting to decide to participate or otherwise. As per consent form it will be very clear to the eligible patient that if they decide not to participate this will not affect any aspect of their ongoing treatment under Professor Sherif Sultan.



6.9 Baseline Data

All participants will undergo a limited medical history as well as functional ambulatory and physical activity measurements. All baseline measurements in the first session and second session will take roughly 90 minutes. This includes isokinetic testing (32 minutes), muscle strength measurements and functional ambulatory measurements (10.5 minutes), demonstration of at home structured exercise programme (up to 20 minutes) and five minutes for both questionnaires.

The following measures will be recorded:

1. Gender
2. Date of birth
3. Calf Muscle Pump Function
4. Venous Clinical Severity Score
5. Physical Activity Readiness Questionnaire(PAR-Q)
6. SF-36 Short Form Health Survey
7. Calf Torque
8. Calf Work
9. Calf Power
10. Plantarflexion Range of Motion
11. Dorsiflexion Range of Motion
12. 6-Minute Walk Test
13. Right Single Leg Balance
14. Left Single Leg Balance
15. Sit-to-Stand
16. Step-Overs
17. Right Single Arm Bicep Curl
18. Left Single Arm Bicep Curl
19. Right Single Arm Triceps Extension
20. Left Single Arm Triceps Extension
21. Push Press

6.10 Physical Activity Readiness Questionnaire (PAR-Q)

All patients will complete a Physical Activity Readiness Questionnaire (PAR-Q) prior to participating in the trial. The PAR-Q is designed to determine if physical activity is safe for individuals or if they may need medical clearance from a physician. If a patient fails to complete or pass the PAR-Q they will be ineligible for participation in the trial.

6.11 SF-36 Short Form Health Survey

All patients will complete the SF-36 Short Form Health Survey at baseline and at the completion of the 12-week exercise programme. The SF-36 Short Form Health Survey is utilized to evaluate an individual's quality of life.

6.12 Venous Clinical Severity Score

All patients will complete the Venous Clinical Severity Score at baseline and upon completion of the 12-week study. The Venous Clinical Severity Score will be used to characterized the severity of the patients' chronic venous insufficiency and to monitor any progression made.

6.13 Calf Muscle Pump Function: Duplex Ultrasound Scanning

All patients will undergo a comprehensive duplex ultrasound scanning to determine the nature and extent of venous reflux. The duplex ultrasound will be conducted by Professor Sherif Sultan during a clinical appointment. A repeat of objective measures will be repeated at the completion of their 12-week.

6.14 Biodex Measurements-Isokinetic Testing

All patients will undergo lower limb isokinetic (concentric/concentric) testing using a using a Biodex Multi-joint System^{33,34}. All Biodex testing will be conducted based of evidence based clinical protocols provided by Biodex. Biodex measurements will consist of knee flexion/extension and ankle plantar flexion and dorsiflexion. For knee flexion/extension patients will undergo a bilateral isokinetic 3 speed evaluation to establish goals and monitor progress³³. Patients will move through full range of motion with a percent range of 100 and will be evaluated at three speeds and three repetitions³³. At 60°/second the patient will complete 5 repetitions, at 180°/ seconds the patient will complete 10 repetitions and at 300°/second the patient will complete

15 repetitions³³. Ankle plantar flexion and dorsiflexion will be measured with a bilateral isokinetic 2 speed evaluation at 5 repetitions at 60°/second and 10 at 120°/second³⁴. Testing will be administered at baseline and at the completion of the 12-week exercise programme; data will be collected and recorded on calf torque, calf work, calf power, plantarflexion range of motion and dorsiflexion range of motion.

6.15 Functional Ambulatory Measurements:

6-minute walk test: All patients will complete a 6-minute walk test on an even/flat 25m ground supervised by a trained exercise technician. Participants will be instructed to walk for 6 minutes at a moderate comfortable rate.

6.16 Physical Activity Measurements

Muscle Endurance Testing

All patients will complete muscular endurance for all major muscles. Patients will be asked to complete a series of upper and lower body exercises testing their muscular endurance within 30 seconds. All patients will complete as many repetitions as they can in 30 seconds at a speed they are comfortable performing at. Muscular endurance testing will be conducted at baseline and upon the completion of the 12-week structured exercise programme. The muscular endurance testing consists of single leg balance on each leg, step overs, sit to stand, push press, single arm right bicep curl, single arm left bicep curl, and single arm right triceps extension and single arm left triceps extension at a moderate rate or intensity.

6.17 Strength From Within Exercise Programme

- All patients will receive the structured exercise programme, and the “Strength From Within Booklet”, a resistance band, a recording booklet, a walking information leaflet, ankle range of motion exercises, a warm-up and a cool-down. The Strength From Within booklet provides a descriptive linguistic and visual demonstration of proper technique and safety for all exercises. The at home resistance exercise programme consists of a total of twenty standing and sitting exercises divided into upper and lower body. Patients will participate in the Strength

From Within structured exercise programme for 12-weeks by choosing their own 5 upper body exercise and 5 lower body exercise per week from the Strength From Within booklet. Patients are able to have a combination of standing and sitting exercises to accommodate their ambulatory needs. Patients will complete lower body exercises on Monday, Wednesday and Friday and complete upper body exercises Tuesday, Thursday and Saturday; Sunday is a rest and recovery day. To further the individualistic aspect of the programme patients will be deciding their own repetitions from a range of eight to twelve, however, the exercise technician will be contacting the patients each week to monitor and implement repetition progression. Progression will be implemented if the patient is able to complete two full weeks of the same repetition count. Built into the exercise programme there will be a dynamic warm-up and static-stretching cooldown, both lasting for five minutes. Ankle range of motion exercises using the resistance band will be included in the exercise programme to be completed on Monday, Wednesday and Friday. Patients will be completing three sets of ten ankle dorsiflexion and plantarflexion with a resistance band. All exercise will be demonstrated and practiced with participants to ensure proper technique and safety. In combination with the Strength From Within programme, patients will participate in a 12-week walking protocol. Each walking protocol will be individualized at the first meeting following the 6-minute walk test. Patients' walking progression will be determined biweekly based on the patients' experience and response to the protocol. Patients will receive a walking protocol recording sheet to fill in the minutes walked each day and the total duration each week. The exercise technician will be referring to the Mayo Clinic 12-week walking protocol for guidance.

Participants will be contacted each week by telephone or personal interaction. Regular weekly check in will be done to know the improvement and status of the participant and to possibly adjust the repetitions and sets to be completed that week accordingly. Upon completion of the study participants will be contacted 3-months after their completion date. Participants will be contacted by telephone and be asked to participate in a short questionnaire on their adherence to the exercise programme after their 12-weeks finished. At the 12-week meeting the study researcher will collect the participants recording booklet in order to evaluate and measure adherence/compliance to the structured exercise programme. Participants have the



right to deny participation in the follow-up questionnaire, if they wish to do so appropriate documentation will be completed to ensure missing data is accounted for. If the study researcher cannot get in touch with the participant on the first attempt to contact the study researcher will call once more a week later. If the study researcher cannot get in contact with the participant after the second attempt the study researcher will not contact that participant again

7. TRIAL OUTCOMES MEASURES

7.1 Primary Outcome Measures

This trial was to determine the effect of a 12-week at home structured exercise and aerobic programme in patients with chronic venous insufficiency. The primary outcome measures is the effect a 12-week at home structured exercise and aerobic programme has on muscle pump function, venous clinical severity score and calf muscle strength in an individuals with chronic venous insufficiency.

7.2 Secondary Endpoints

The following endpoints will be measured:

1. Ankle Joint Range of Motion
2. Overall physical strength
3. Exercise Capacity
4. Quality of life

8 TRIAL OUTCOME ASSESSMENT

Trial outcomes will be recorded on a baseline measurement form developed by the supervising exercise technician.

8.1 Evaluation of Other Primary and Secondary Outcomes

Remaining primary and secondary outcomes will be determined by the blinded trail assessor through data collected.

10 STATISTICAL APPROACH

Graphical and numerical summaries will be provided for all response variables of interest. For categorical variables, test of association will be performed to test for any associated between factors of interests. Chi squared test (using a significance level of 0.05) will be used if the underlying assumption relating to the expected values are deemed appropriate, otherwise Fisher Exact Test will be employed. For binary variables, comparisons of proportion based on the Normal approximation of the Binomial distribution will be used as necessary. P-values will be reported for those comparisons of specific interest as opposed to comparing all levels of all variables. And post intervention scores will be compared. Baseline characteristics of the participants and physical activity levels will be compared from week one of the study, to week 12 the completion of the study. Duration of the obtaining baseline data and final data will be measured. An ANVOA will be performed to analyse change over time. The outcomes will be found by using a paired t test. Mean baseline values will be computed from both duplex ultrasound screening and Biodex. Treatment effects will be estimated by an analysis variance (ANOVA).

11 SAMPLE SIZE

The primary outcome for this trial is the effect a 12-week at home structured resistance and aerobic exercise programme has on muscle pump function, venous clinical severity score and calf muscle strength in an individuals with chronic venous insufficiency. Research suggest that participation in a structured exercise programme has the ability to improve calf muscle pump function and dynamic calf strength^{23,29}. As a pilot study 60 participants will be recruited; with intention of 30 participants completing the trial; previous pilot studies conducted similar to this trial have used similar sample size.

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Mayo Clinic 12 Week Walking Protocol³⁵

Week	Minutes
1	5 minutes
2	7 minutes
3	9 minutes
4	11 minutes
5	13 minutes
6	15 minutes
7	18 minutes
8	20 minutes
9	23 minutes
10	26 minutes
11	28 minutes
12	30 minutes



Warm-up: 5 minutes

▪ **March in place 20 times**

Step 1: Stand upright, (shoulders back, abs tightened, and no arch in the lower back)

Step 2: Lift right leg, lower right leg; lift left leg, lower left leg



▪ **Arm circles both 10 each direction**

Step 1: Start by standing straight with your feet shoulder width apart. Arms should be straight out to the sides, so that your body forms a T.

Step 2: Slowly start by making small circular motions with both arms on either side. After a few repetitions of small circles, enlarge your circles and do the same amount of reps.



▪ **Hip Rotation 10 each direction**

Step 1: Start by standing straight with your feet shoulder width apart. Place hands on your hips.

Step 2: Begin to rotate your hips in a clockwise direction, then switch to counter-clock wise.



▪ Side step with arms up 10 each direction

Step 1: Start by standing straight with your feet together with a strong tall body.

Step 2: Step out with your left foot and raise hands up as you step out. Then switch to stepping with your right foot.



▪ Cross step cross arm 10 total

Step 1: Start by standing straight with a wide stance and a slight bend at your knees.

Arms should be out straight to the side so your body is forming a T.

Step 2: Alternate legs and arms as you cross.



▪ Heel to butt steps 10 each side

Step 1: Holding onto a firm object have a slight bend at the knees while leaning forward.

Step 2: Bend on knee at a time bringing your heel towards you backside.





▪ **March 20 times**

Step 1: Stand upright, (shoulders back, abs tightened, and no arch in the lower back)

Step 2: Lift right leg, lower right leg; lift left leg, lower left leg



Cool Down (2 sets 30 seconds each)

▪ **Quadriceps Stretch:**

Step 1: Stand up right with weight balance on left leg. Keep left foot pointing straight and the knee almost straight. To help with balance use a wall or firm object for assistance.

Step 2: Bend the right knee; grasp the right foot and pull the heel backward.

Step 3: At the same time push forward at the hips. Complete set and then perform stretch to the opposite leg.



▪ **Hamstring Stretch:**

Step 1: Stand upright with weight balanced on left leg. Bend at the right hip and place the right leg on firm object that is close to the same height as your hips.

Step 2: Bend at the waist and reach for your toes and keep left leg straight. Complete set and then perform stretch to the opposite leg.





▪ Inner Thigh Stretch:

Step 1: Sit comfortably with your legs at a 90-degree angle and bent at the waist with your chest parallel to the floor.

Step 2: As you lean forward use your elbows or forearms to cause a stretch in the inner thigh area. Complete set and then perform stretch to the opposite leg.



▪ Bicep Stretch:

Step 1: Extend one arm and flex the wrist at the same time. Use the opposing hand to grasp the fingers and pull the fingers toward the body. Complete set and then perform stretch to the opposite arm.



▪ Triceps Stretch:

Step 1: Sit or stand upright with the left arm bent at the elbow. Raise the left arm until the elbow is next to the left ear and the left hand is near the right shoulder blade.

Step 2: Grasp the left elbow with the right hand and pull or push the left elbow behind the head and toward the floor. Complete set and then perform stretch to the opposite arm.



▪ Chest Stretch



Step 1: Stand upright while facing a doorway or corner. Place feet shoulder width apart with one foot slightly in front of the other.

Step 2: With straight arms, raise your arms to shoulder level and place the palms on the wall or doorframe with the thumbs on top. Lean your body forward, and complete set and then perform stretch to the opposite arm.





Ankle Range of Motion Exercises

3 Sets of 10 for each ankle

3 days per-week

Equipment: Resistance (elastic band)

Plantarflexion

Step 1: Sit on the floor or a bed with your back supported and your legs straight out in front of you

Step 2: Wrap the resistance band around your foot and hold each end of the resistance band in your hands

Step 3: Have your ankle held up towards your head and slowly move your foot and ankle against the resistance band

Step 4: Slowly return to the starting position and repeat 10 times

Tip: Keep your leg straight and heel on the floor for support. To increase resistance, move your hands down the resistance band toward your foot

Dorsiflexion

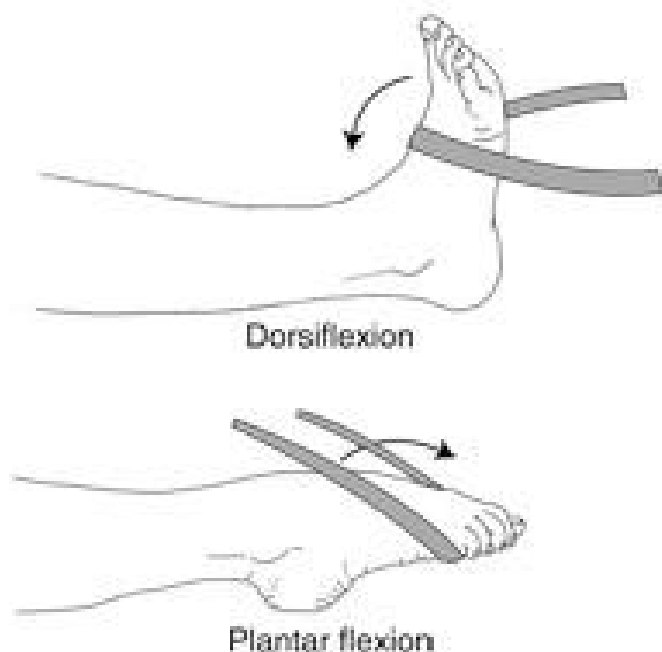
Step 1: Sit on the floor or a bed with your back supported and your legs straight out in front of you

Step 2: Anchor the elastic band on a chair, table leg, or have another individual hold it for you.

Step 3: Pull your toes toward you and slowly return to the starting position.

Step 4: Repeat 10 times

Tip: Keep your leg straight and heel on the floor for support.





Biodex Clinical Protocol for testing Knee Flexion/Extension and Ankle Plantarflexion/Dorsiflexion: Testing Gastrocnemius and Soleus Strength

Knee Flexion/Extension²⁴

- Bilateral Isokinetic 3 speed Evaluation
 - Biodex Multi-joint System
 - Concentric/Concentric
 - To establish goals and monitor progress
 - Instruct patient to perform through full ROM
- Isokinetic Evaluation 3 Speed:
 - Full Active ROM
 - 100% Range
 - Reps & Speeds:
 - 5@ 60 deg/sec
 - 10 @180 deg/sec
 - 15 @300 deg/sec

Ankle Plantarflexion/Dorsiflexion²⁵

- Bilateral Isokinetic 2 speed evaluation
 - Biodex Multi-joint System
 - Concentric/Concentric
- Isokinetic Evaluation 2 Speed:
 - Patient supine, support under distal femur, knee flexed to 10deg
 - Reps & Speeds:
 - 5 @ 60 deg/sec
 - 10 @ 120 deg/sec



PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	1. Has your doctor ever said that you have a heart condition <u>and</u> that you should only do physical activity recommended by a doctor?
<input type="checkbox"/>	<input type="checkbox"/>	2. Do you feel pain in your chest when you do physical activity?
<input type="checkbox"/>	<input type="checkbox"/>	3. In the past month, have you had chest pain when you were not doing physical activity?
<input type="checkbox"/>	<input type="checkbox"/>	4. Do you lose your balance because of dizziness or do you ever lose consciousness?
<input type="checkbox"/>	<input type="checkbox"/>	5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?
<input type="checkbox"/>	<input type="checkbox"/>	6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
<input type="checkbox"/>	<input type="checkbox"/>	7. Do you know of <u>any other reason</u> why you should not do physical activity?

If
you
answered

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active — begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal — this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- If you are not feeling well because of a temporary illness such as a cold or a fever — wait until you feel better; or
- If you are or may be pregnant — talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____

DATE _____

SIGNATURE OF PARENT
or GUARDIAN (for participants under the age of majority) _____

WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.





...continued from other side

PAR-Q & YOU

Physical Activity Readiness
Questionnaire - PAR-Q
(revised 2002)

Physical Activity Guide to Healthy Active Living

Physical activity improves health.

Every little bit counts, but more is even better—everyone can do it!

Get active your way—
build physical activity
into your daily life...

- at home
- at school
- at work
- at play
- on the way
- ...that's active living!

to Healthy Active Living

Increase
endurance
activities

Increase
flexibility
activities

Increase
strength
activities

Reduce
risk of
long periods

Choose a variety of
activities from these
three groups:

Endurance

4-7 days a week
Continuous activities
for your heart, lungs
and circulatory system.

Flexibility

4-7 days a week
Gentle stretching, bending
and stretching activities to
keep your muscles relaxed
and joints mobile.

Strength

2-4 days a week
Activities against resistance
to strengthen muscles and
bones and improve posture.

Starting slowly is very
safe for most people.
Not sure? Consult your
health professional.

For a copy of the
Guide booklet and
more information:
1-888-334-9768, or
www.papguide.com

Eating well is also
important. Follow
Canada's Food Guide to
make wise food choices.

Get Active Your Way. Every Day—For Life!

Scientists say accumulating 10 minutes of physical activity
every day to stay healthy or improve your health. As
you progress to moderate activities you can cut down to
10 minutes, 4 days a week. Add-up your activities in periods
of at least 10 minutes each. Start slowly... and build up.

Time needed depends on effort				
Very Light Effort	Light Effort	Moderate Effort	Vigorous Effort	Maximum Effort
• Walking • Bicycling	• Light walking • Bicycling • Easy gardening • Swimming • Water aerobics	• Brisk walking • Biking • Jogging • Dancing • Fast swimming • Fast dancing	• Aerobics • Running • Football • Field hockey	• Sprinting • Boxing

Range needed to stay healthy

You Can Do It - Getting started is easier than you think

Physical activity doesn't have to be very hard. Build physical
activities into your daily routine.

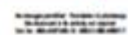
- Walk whenever you can—get off the bus early, use the stairs instead of the elevator.
- Reduce inactivity for long periods, like watching TV.
- Get up from the couch and stretch and bend for a few minutes every hour.
- Play actively with your kids.
- Choose to walk, wheel or cycle for short trips.
- Start with a 10 minute walk—gradually increase the time.
- Find out about walking and cycling paths nearby and use them.
- Observe a physical activity class to see if you want to try it.
- Try one class to start—you don't have to make a long-term commitment.
- Do the activities you are doing now, more often.

Benefits of regular activity:

- Better health
- Improved bones
- Lower pressure and better blood circulation
- Lower cholesterol
- Stronger muscles and bones
- Feeling more energetic
- Reduced risk of heart disease
- Reduced risk of osteoporosis
- Better sleep

Health risks of inactivity:

- Premature death
- Heart disease
- Obesity
- High blood pressure
- Arteriosclerosis
- Osteoporosis
- Stroke
- Colon cancer



Source: Canada's Physical Activity Guide to Healthy Active Living, Health Canada, 1998 <http://www.hc-sc.gc.ca/hppb/paguide/pdf/guideEng.pdf>

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FITNESS AND HEALTH PROFESSIONALS MAY BE INTERESTED IN THE INFORMATION BELOW:

The following companion forms are available for doctors' use by contacting the Canadian Society for Exercise Physiology (address below):

The **Physical Activity Readiness Medical Examination (PARmed-X)** —to be used by doctors with people who answer YES to one or more questions on the PAR-Q.

The **Physical Activity Readiness Medical Examination for Pregnancy (PARmed-X for Pregnancy)** —to be used by doctors with pregnant patients who wish to become more active.

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- Thomas, S., Reading, I., Shephard, R.J. (1992). Revision of the Physical Activity Readiness Questionnaire (PAR-Q). *Can. J. Sport Sci.* 17:4 338-345.

For more information, please contact the:

Canadian Society for Exercise Physiology
202-185 Somerset Street West
Ottawa, ON K2P 0J2
Tel. 1-877-651-3755 • FAX (613) 234-3565
Online: www.csep.ca

The original PAR-Q was developed by the British Columbia Ministry of Health. It has been revised by an Expert Advisory Committee of the Canadian Society for Exercise Physiology chaired by Dr. N. Gedhill (2002).

Disponible en français sous le titre «Questionnaire sur l'aptitude à l'activité physique - Q-AAP (révisé 2002)».



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Health
Canada

Santé
Canada



SF-36® Health Survey Scoring Demonstration

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c Lifting or carrying groceries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d Climbing <u>several</u> flights of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e Climbing <u>one</u> flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f Bending, kneeling, or stooping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g Walking <u>more than a mile</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h Walking <u>several blocks</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i Walking <u>one block</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j Bathing or dressing yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a Cut down on the <u>amount of time</u> you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
b <u>Accomplished less</u> than you would like	<input type="radio"/>	<input type="radio"/>
c Were limited in the <u>kind</u> of work or other activities	<input type="radio"/>	<input type="radio"/>
d Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	<input type="radio"/>	<input type="radio"/>

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a Cut down on the <u>amount of time</u> you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
b <u>Accomplished less</u> than you would like	<input type="radio"/>	<input type="radio"/>
c Did work or other activities <u>less carefully than usual</u>	<input type="radio"/>	<input type="radio"/>

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a Did you feel full of pep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b Have you been a very nervous person?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c Have you felt so down in the dumps that nothing could cheer you up?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d Have you felt calm and peaceful?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e Did you have a lot of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f Have you felt downhearted and blue?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g Did you feel worn out?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h Have you been a happy person?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i Did you feel tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b I am as healthy as anybody I know	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c I expect my health to get worse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d My health is excellent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



VENOUS CLINICAL SEVERITY SCORE

ATTRIBUTE	ABSENT=0	MILD=1	MODERATE=2	SEVERE=3
PAIN	NONE	OCCASIONAL, NOT RESTRICTING ACTIVITY OR REQUIRING PAIN MEDICATION	DAILY MODERATE ACTIVITY LIMITATION; OCCASIONAL PAIN MEDICATION	DAILY, SEVERE LIMITING ACTIVITIES OR REQUIRING REGULAR USE OF PAIN MEDICATIONS
VARICOSE VEINS	NONE	FEW SCATTERED	MULTIPLE; GREAT SAPHENOUS VEINS, CONFINED TO CALF AND THIGH	EXTENSIVE; THIGH AND CALF OR GREAT AND SMALL SAPHENOUS DISTRIBUTION
VENOUS EDEMA	NONE	EVENING ANKLE SWELLING ONLY	AFTERNOON SWELLING, ABOVE ANKLE	MORNING SWELLING ABOVE ANKLE AND REQUIRING ACTIVITY CHANGE, ELEVATION
SKIN PIGMENTATION	NONE	DIFFUSE, BUT LIMITED IN AREA AND OLD (BROWN)	DIFFUSE OVER MOST OF GAITER DISTRIBUTION (LOWER THIRD) OR RECENT PIGMENTATION (PURPLE)	WIDER DISTRIBUTION (ABOVE LOWER THIRD) PLUS RECENT PIGMENTATION
INFLAMMATION	NONE	MILD CELLULITIS, LIMITED TO MARGINAL AREA AROUND ULCER	MODERATE CELLULITIS, INVOLVES MOST OF (LOWER THIRD)	SEVERE CELLULITIS (LOWER THIRD AND ABOVE) OR SIGNIFICANT
INDURATION	NONE	FOCAL, CIRCUMALLEOLAR	MEDIAL OR LATERAL, LESS THAN LOWER THIRD OF LEG	ENTIRE LOWER THIRD OF LEG OR MORE
NUMBER OF ACTIVE ULCERS	0	1	2	>2
ACTIVE ULCER DURATION	NONE	<3 MONTHS	>3 MONTHS, <1YEAR	NOT HEALED>1 YEAR
ACTIVE ULCER DIAMETER	NONE	<2	2-6	>6
COMPRESSION THERAPY	NOT USED OR PATIENT NOT COMPLIANT	INTERMITTANT USE OF STOCKINGS	WEARS ELASTIC STOCKING MOST DAYS	FULL COMPLIANCE, STOCKINGS+ELEVATION



PARTICIPANT INFORMED CONSENT

Effect of Structured Exercise in Individuals with Chronic Venous Insufficiency

Date: 26.10.2017

Introduction:

You are invited to participate in our research study. This research study aims to examine if a special exercise programme, called “Strength from within” can improve calf muscle strength and function, overall physical strength, movements of the ankle joint and have a positive impact on quality of life. This study is being done as we know that improvement in calf muscle strength can improve the flow of blood in veins in patients with varicose veins. Therefore, we want to see if our exercise programme carried out at home can also benefit patients with varicose veins. During this study, you will complete a questionnaire regarding your quality of life (at the beginning and end of the study) and answer questions on symptoms you may have due to your varicose veins. Measurements will be taken of your calf muscle strength and function, overall physical strength and movements of the ankle joint by the study researcher. These measures will be taken again at the end of the study (week 12). If you have any further questions do not hesitate to ask.

Procedure:

You will be shown how to do the exercises by the study researcher and asked to carry this out 6 days a week at home at a time that suits you. Clear instructions and demonstration of the exercises will be given to you at the start of the study. Also, a programme of which exercises and how much you exercise will be provided to you according to your capabilities. You will also be given the exercise brochure called “Strength from within” which shows all exercises and how to do these. Finally, you will be asked to keep a record of your exercises during the study.

The study researcher will contact you each week at a time that suits you to check on your week’s exercise plan and make adjustment for the next week. The study researcher will keep a record of your exercise plan for each week.

Benefits and Risks for participants:

The findings of this study will be presented to the team of the healthcare professionals involved at the Galway Clinic and University Hospital Galway. This research may help improve your calf muscle strength and function, reduce symptoms of varicose veins, overall physical strength and have a positive impact on your quality of life. Other benefits you may have from doing exercises in this study are lowering your risk of cardiovascular disease, stress reduction, possible weight loss, reduced cholesterol levels, reduce your risk of developing type 2 diabetes and lowering of your blood pressure. The structured exercise programme does not exceed international recommendations and guidelines for adults by the American College of Sport’s Medicine.

With any exercise, there is the possibility that abnormal responses could occur. While these risks are low for this type of exercise, they can include: unexpected changes in blood pressure, irregular heart rate, shortness of breath, fatigue, muscle cramps, muscle soreness, or joint injury, and in rare cases, a cardiac event. Investigators will have evaluated you using



a pre-study health screening to ensure that you do not have a health condition where exercise is contraindicated. Risks will be minimized through an exercise plan which contains a standard exercise protocol, with a warm-up and cool-down at the start and end of each exercise session carried out by you. Participants are instructed to stop the program if they are having any abnormal responses and contact the principal investigator.

Compensation:

No tangible compensation will be given.

Confidentiality:

Any information obtained during this study, which could identify you will be kept confidential. Information may be published in professional/scientific journals or at professional meetings, however your identity will be kept strictly confidential by a coded procedure.

Right to Refuse or Withdrawal:

I understand that it is my responsibility to notify the researcher if I experience any abnormal responses during or following the program. I will do what I think is safe for myself and will not exceed these limits. I understand that I have the right to refuse to participate or withdraw from participation of this study at any time without penalty. I know I may change my mind about being in the study or withdraw from the study after it begins. If the study design or use of the data changes I will be informed and consent be revised.

Name Printed

Signature & Date

Researcher's Signature & Date



PARTICIPANT INFORMATION LEAFLET

Effect of Structured Exercise in Individuals with Chronic Venous Insufficiency

Date: 26.10.2017

Introduction:

You are invited to participate in our research study. This research study aims to examine if a special exercise programme, called “Strength from within” can improve calf muscle strength and function, overall physical strength, movements of the ankle joint and have a positive impact on quality of life. This study is being done as we know that improvement in calf muscle strength can improve the flow of blood in veins in patients with varicose veins. Therefore, we want to see if our exercise programme carried out at home can also benefit patients with varicose veins. During this study, you will complete a questionnaire regarding your quality of life (at the beginning and end of the study) and answer questions on symptoms you may have due to your varicose veins. Measurements will be taken of your calf muscle strength and function; overall physical strength and movements of the ankle joint by the study researcher. These measures will be taken again at the end of the study (week 12). If you have any further questions do not hesitate to ask.

Procedure:

You will be shown how to do the exercises by the study researcher and asked to carry this out 6 days a week at home at a time that suits you. Clear instructions and demonstration of the exercises will be given to you at the start of the study. Also, a programme of which exercises and how much you exercise will be provided to you according to your capabilities. You will also be given the exercise brochure called “Strength from within” which shows all exercises and how to do these. Finally, you will be asked to keep a record of your exercises during the study.

The study researcher will contact you each week at a time that suits you to check on your week’s exercise plan and make adjustment for the next week. The study researcher will keep a record of your exercise plan for each week.

Session Two will occur after the completion of your 12-weeks. At this session, you will complete a questionnaire on your quality of life and will be asked a few questions on your symptom. The study researcher will collect your recording booklet, but you are welcome to keep your strength from within booklet and resistance band. Three months after you have completed the study the study researcher will contact you by phone to complete a questionnaire.

Benefits and Risks for participants:

The findings of this study will be presented to the team of the healthcare professionals involved at the Galway Clinic and University Hospital Galway. This research may help improve your calf muscle strength and function, reduce symptoms of varicose veins, overall physical strength and have a positive impact on your quality of life. Other benefits you may have from doing exercises in this study are lowering your risk of cardiovascular disease, stress reduction, possible weight loss, reduced cholesterol levels, reduce your risk of developing type 2 diabetes and lowering of your blood pressure. The structured exercise programme does not



exceed international recommendations and guidelines for adults by the American College of Sport's Medicine.

With any exercise, there is the possibility that abnormal responses could occur. While these risks are low for this type of exercise, they can include: unexpected changes in blood pressure, irregular heart rate, shortness of breath, fatigue, muscle cramps, muscle soreness, or joint injury, and in rare cases, a cardiac event. Investigators will have evaluated you using a pre-study health screening to ensure that you do not have a health condition where exercise is contraindicated. Risks will be minimized through an exercise plan which contains a standard exercise protocol, with a warm-up and cool-down at the start and end of each exercise session carried out by you. Participants are instructed to stop the program if they are having any abnormal responses and contact the principal investigator.

Confidentiality:

Any information obtained during this study, which could identify you will be kept confidential. Information may be published in professional/scientific journals or at professional meetings, however your identity will be kept strictly confidential by a coded procedure.

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I understand that it is my responsibility to notify the researcher if I experience any abnormal responses during or following the program. I will do what I think is safe for myself and will not exceed these limits. I understand that I have the right to refuse to participate or withdraw from participation of this study at any time without penalty. I know I may change my mind about being in the study or withdraw from the study after it begins. If the study design or use of the data changes I will be informed and consent be revised.

Please contact researcher for any further questions.



Physical Activity Levels in Individuals with Chronic Venous Insufficiency

Questionnaire: please answer all questions. If you have any questions please ask the researcher. All information gathered will be recorded anonymously.

Study Researcher Purpose Only
Trial ID:

1) Age _____ years

2) What is your gender?

☐

Female

☐

Male

3) Do you wear compression stockings?

☐

Yes

☐

No (skip question 4 if no)

4) If yes, how many hours a day do you wear compression stockings?

☐

0-6

☐

6-12

☐

12-18

☐

18-24

5) What type of setting do you live in?

☐

Rural Setting

☐

Suburb Setting

6) Overall, how would you categorize your current health status?

☐

Excellent

☐

Very Good

☐

Good

☐

Fair

☐

Poor

7) What is your main form of transport?

☐

Car

☐

Bus

☐

Train

☐

Taxi/Car Service

☐

Other



8) During your day, which of the following best describes what you do?

- ☐ Mostly sitting or standing
- ☐ Mostly Walking
- ☐ Mostly heavy labour or physically demanding

9) How often do you exercise? (not including labour done at work)

- ☐ Never
- ☐ A few times per month
- ☐ A few times per week
- ☐ Almost every day

10) If you do exercise, how long do you spend exercising each day?

- ☐ 10-20 minutes
- ☐ 20-30 minutes
- ☐ 30-60 minutes
- ☐ 60+ minutes

11) What type of exercise do you do? (Tick all that apply)

- ☐ Walking
- ☐ Jogging
- ☐ Swimming
- ☐ Biking
- ☐ Weightlifting
- ☐ Yoga/Pilates
- ☐ Gym Class (spin, HIIT, etc.)
- ☐ Other _____



12) Do you feel your physical activity levels are sufficient to benefit your health status?

Yes ☐

No ☐

Don't know ☐

13) Do you feel that physical activity can positively affect your health?

Yes ☐

No ☐

Don't know ☐

14) If you are currently diagnosed with any of the conditions listed below please tick the box (tick all that apply to you)

☐ Obesity

☐ Hypertension (high blood pressure)

☐ Venous Thrombosis

☐ Coronary Heart Disease

☐ Diabetes

☐ Arthritis

☐ Dyspnea (difficulty breathing)

☐ Angina

☐ Asthma



Three-Month Follow Up to Exercise in Individuals with Chronic Venous Insufficiency

Questionnaire: please answer all questions. If you have any questions please ask the researcher. All information gathered will be recorded anonymously.

1) Age _____ years

2) What is your gender?

☐

Female

☐

Male

3) Do you walk during the week?

☐

Yes

☐

No

4) If yes, how many minutes a week do you walk roughly

☐

10-20 minutes

☐

20-30 minutes

☐

30-60 minutes

☐

60+ minutes

5) During your day, which of the following best describes what you do?

☐

Mostly sitting or standing

☐

Mostly Walking

☐

Mostly heavy labour or physically demanding

6) How often do you exercise? (not including labour done at work)

☐

Never

☐

A few times per month

☐

Study Researcher Purpose Only
Trial ID:



A few times per week

☐ Almost every day

7) If you do exercise, how long do you spend exercising each week?

☐ 10-20 minutes

☐ 20-30 minutes

☐ 30-60 minutes

☐ 60+ minutes

8) What type of exercise do you do? (Tick all that apply)

☐ Walking

☐ Jogging

☐ Swimming

☐ Biking

☐ Weightlifting

☐ Yoga/Pilates

☐ Gym Class (spin, HIIT, etc.)

☐ Strength From Within Programme

☐ Other _____

9) Do you feel your current physical activity levels are sufficient to benefit your health status?

Yes ☐

No ☐

Don't know ☐

10) Do you feel that physical activity has positively affected your health?




Yes ☐

No ☐

Don't know ☐

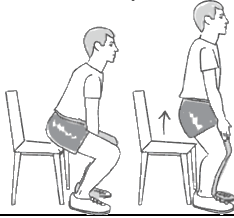


Baseline Recording Chart

Trial ID:		Week Of Baseline:	
Date:			
6 Minute Walk Test: 		<div>Laps:</div> <div>Total:</div>	
Single Leg Balance (30 seconds): 		<div>Right Leg:</div> <div>Left Leg:</div>	
Step Overs (30 seconds): 		<div>Total Number of Step Overs:</div>	



Sit To Stand (30 seconds):



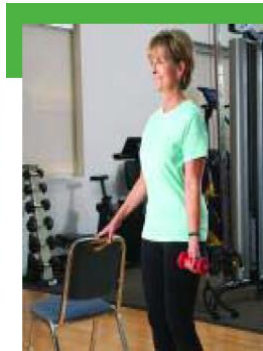
Total:

Push Press (30 seconds):



Total:

Bicep Curl (30 Seconds):



Right Arm:

Left Arm:

Triceps Extension (30 seconds):



Right Arm:

Left Arm:



Biodex Information Sheet

1. Turn on system
2. Calibrate Biodex, reconnect with biodex (click blinking start)
3. Knob will turn and calibrate on dynamometer
4. Check list is on the left side on the pop up on the computer
5. Patient information (first and last name, gender, involved leg if injured)
 - a. For our trial hit NONE
6. Need to add weight
7. ID Number and click save
8. Second tab on the left side still is your protocol tab
 - a. Protocol is dependent on situation and test
9. Options will come up and select **Isokinetic Bilateral**
10. Select knee and ankle
11. Hit done
12. Bottom black knob allows the whole unit to turn around to test opposite leg
13. Set up to 90° when changing from right to left and left to right and lock the device in
14. To move the whole machine to test opposite leg, step on the small steps behind the platform and slide the device across the chair
15. **SEAT SET UP**
16. Have patient sit in the chair
17. Step on lever at the side of the chair and pull chair forward to have the ability to go around the entire chair
18. Have the patient bring their hips all the way to the back of the chair and be sitting flat
19. Looking for two finger width of space from the back of the knee to the chair
 - a. Needs to be able to have full EXT/FLEX
20. To move the patient forward or backward on the chair use the circular handle on the back of the chair that will produce that action
21. Have the patient readjust and hips are all the way back
22. Shoulder, hip, leg and ankle strap
23. Bring the strap down to the clasp
 - a. Shoulder straps go to the back claps, have the strap snug but not tight
 - b. Ask the patient: does that feel comfortable? It is going to be snug but should not be hurting
 - c. Waist strap over the hips into the clasp on the chair, tight but not debilitating
 - i. Reason for the straps: making sure the leg is the only thing generating momentum
24. **SET UP DYNAMOMETER**
 - a. On each handle has the corresponding marking for each leg
 - b. Ankle should be going right on the ankle pad
 - c. Place the handle into the dynamometer
 - d. Use the black screw knob to lock in the handle to the dynamometer
 - e. Have the patient rest their leg on the ankle pad and move the chair forward to line the knee with the black knob for an axis of rotation
 - f. The leg should be close but not rubbing against the black knob
 - g. Thigh strap goes over the leg that is being tested, tight but snug.



- i. Tight as they are comfortable with
- h. Ankle strap goes across the leg with the ankle pad sitting right on the back of the ankle
 - i. The pad can be moved if adjusting is needed with the black knob half way down the bar

25. BACK TO THE COMPUTER

- a. SET ROM (looks like a T)
- b. Yes, to ROM limits
- c. Press the computer control button
- d. Automatically take to the next screen
- e. Make sure you have the correct leg selected
- f. Ability to move the leg in and out
- g. Set the away and toward limits
- h. Hold clicker
- i. Instruct the patient to kick their leg out as far as they can
- j. Hold the leg and click the clicker to lock patient in
- k. Computer will say AWAY limit and click SET
- l. After hit set, use the click to set free
- m. As the leg is set free instruct the patient to pull their leg as far in as they can
- n. Lock patient in
- o. Set toward limit
- p. On the screen, it has a red A&T
 - i. Means leg was properly set
 - ii. Hit continue to free the leg

26. SET NATURAL 90°

- a. Instruct the patient to take a deep breath and let their leg hang naturally
- b. Click the T to set his natural range or natural 90°

27. WEIGH THE LEG

- a. Instruct the patient to kick their leg out as far as they can and hold it
- b. Lock the patient in by the clicker
 - i. And relax
- c. Instruct the patient to take a deep breath in and relax completely to weigh the leg
- d. Hit the scale that says limb weight
 - i. Important: because if they are putting any type of pressure on the pad they will increase the leg any contraction will weigh less
 - ii. The machine will add and correct for it when measure for power, work, torque etc.

28. READY TO START THE TEST

- a. Before starting the test be sure to explain the test to the subject
 - i. Knee FLEX/EXT
 - 1. You will be going through three evaluating speeds **on each leg**
 - 2. The first one will be 60° per second and you will complete 5 repetitions.
 - 3. 30-60 second break
 - 4. Second speed will be at 180° per second with 10 repetitions
 - 5. 30-60 second break



6. The third and final speed will be a 300° per second with 15 repetitions
7. Break
- ii. Ankle plantar flexion/dorsiflexion
 1. You will be going through 2 evaluating speeds **on each leg**
 2. The first test will be at 60° per second with 5 repetitions
 3. 30-60 second break
 4. The second speed will be at 120° per second with 10 repetitions
- b. The GO button will not start the test the test starts when the subject stops moving the leg
 - i. Give the patient a test runs
 1. One at 50%, 75% and 100% (respectively)
 - ii. After the three tests runs are done have the patient pull the leg back completely and hold the leg back to start the leg
- c. The computer will tell you when to go
- d. Encourage the patient and follow the progress on the screen
- e. DO NOT TELL THE PATIENT WHERE THEY ARE IN REPETITIONS
 - i. Can affect the end result
- f. Computer will hit 100% done
- g. Immediately when FINISHED unstrapping the patient so they are free and bale to relax
- h. Instruct the patient to come out of the chair carefully and assist them to a resting point
- i. Computer will say all sets have been complete and hit YES to finish the test
- j. The last step
 - i. Hit report
 - ii. Comprehensive evaluation
 - iii. Use metric units
 - iv. Print, OK
 - v. Reports will be generated

29. Tip on results

- a. All reps will be given
- b. Graph will show a fatigue
 - i. Should start high and end low
 - ii. If it starts low and goes high something went wrong